# EXHIBIT F

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>**Terreski Mullins, et al. v. Ethicon, Inc., et al.**<br>**Civil Action No. 2:12-cv-02952** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**PLAINTIFFS' REPLY TO DEFENDANTS RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION AND MEMORANDUM TO EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENDANT ETHICON, INC.'S EXPERT STEVEN MACLEAN, PH.D., P.E.**

Scientists from around the world, including Ethicon's own scientists, have demonstrated time and time again that polypropylene, including PROLENE, undergoes surface degradation after it is implanted in the body.[1,2,3,4,5,6,7,8,9,10,11,12] This opinion was confirmed by Ethicon's

[1] Exhibit A – Liebert, et al., "Subcutaneous Implants of Polypropylene Filaments." *Journal of Biomedical Materials Research*, (1976) 10(6):939–951
[2] Exhibit B – Jongebloed et al., "Mechanical and biochemical effects of man-made fibers and metals in the human eye, a SEM-study, *Documenta Ophthalmologica* (1986) 61, 303-3012
[3] Exhibit C – Mary, et al., "Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery" *ASAIO Journal*, (1998) 44(3):199–206
[4] Exhibit D – Clavé, et al., "Polypropylene as a Reinforcement in Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants." *Int. Urogynecology J.*, (2010) 21(3):261–270
[5] Exhibit E – Costello, et al., "Characterization of Heavyweight and Lightweight Poly." *J. Biomed. Mater. Res. B Appl. Biomater.*, (2007) 83B(1):44–49; Costello et al., "Materials Characterization of Explanted Polypropylene Hernia Meshes," *J. Biomed. Mater. Res. B Appl. Biomater.*, (2007) 83B(1):44–49.
[6] Exhibit F – Wood, et al. "Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient." *J. Mater. Sci. Mater. Med.*, (2013) 24(4):1113–1122
[7] Exhibit G – Crack Depth In Explanted Prolene Sutures (June 15, 1982), ETH.MESH.12831405
[8] Exhibit H – Prolene (Polypropylene) Microcracks memo (March 23, 1983), ETH.MESH.15955438
[9] Exhibit I – Human Retrieval Specimens From Dr. Roger Gregory, Norfolk Surgical Group memo (March 29, 1983), ETH.MESH.15955440 (Ethicon's scientists used the same histological methods employed by Dr. Iakovlev to identify surface cracks observed on explanted Prolene sutures)
[10] Exhibit J – Examination of Prolene (Polypropylene) Sutures from Human Cardiovascular Explants memo (May 2, 1984) , ETH.MESH.15955462 (Ethicon's scientists using the same histological methods

former scientist Dr. Thomas Barbolt who testified on behalf of Ethicon as its 30(b)(6) witness and admitted that the PROLENE polypropylene material used to manufacture the TVT devices undergoes *in vivo* surface degradation:

> **Q. And that's Ethicon's position as you – as the spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct?**
>
> **A. Yes.**[13]

Despite the overwhelming evidence that PROLENE degrades *in vivo*, the Defendants designated Dr. MacLean to rebut the conclusions of all of these scientists and the expert opinion testimony offered by Plaintiffs' experts who have concluded that polypropylene, including PROLENE, used by Ethicon to manufacturer TVT is subject to *in vivo* oxidative degradation. In support of his opinions Dr. MacLean served two expert reports: 1) Dr. MacLean's Microscopy Report Report and 2) Dr. MacLean's General Report.

On October 22, 2015, the Plaintiffs filed their Motion and Memorandum to Exclude the Opinions and Testimony of Defendant Ethicon, Inc.'s Expert Steven MacLean (referred to herein as Motion).[14] Plaintiffs moved to exclude or to limit the testimony of Dr. MacLean on several grounds, including: 1) his lack of qualifications to offer opinions regarding biocompatibility, chemistry, pathology or regulatory issues;[15] 2) his experiment is unreliable; and 3) his opinions based on the molecular weight data from Ethicon's Seven-Year Dog Study are unreliable.

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as Dr. Iakovlev found that the explanted PROLENE suture had degraded in vivo. The histological stain penetrated the degraded PROLENE fiber. Blue dye particles were observed within the cracked layer confirming that cracked layer was PROLENE polypropyrlene and not a protein coating on the PROLENE strands)

[11] Exhibit K – IR Microscopy of Explanted PROLENE Received from Prof. R. Guidoin (Sept. 30, 1987), ETH.MESH.12831391-1404

[12] Exhibit L – Seven Year Dog Study (Prolene 7-Year Dog Study) (Oct. 15, 1992), at ETH.MESH.09888220

[13] Deposition of Thomas Barbolt, Ph.D., January 8, 2014, at 409:2-8

[14] Mullins, et al. v. Ethicon, Inc. et al, 2:12-cv-02952, Doc. 139 (Oct. 22, 2015)

[15] The Defendants have represented in their Response that Dr. MacLean will not offer opinions regarding biocompatibility or regulatory issues. See Response at p. 6.

On November 9, 2015, the Defendants filed their Response in Opposition to Plaintiffs' Motion and Memorandum to Exclude the Opinions and Testimony of Defendant Ethicon, Inc.'s Expert Steven MacLean, Ph.D., P.E. (hereinafter referred to as "Response").[16] Defendants' argue in their Response that: 1) Dr. MacLean is qualified to offer polymer science opinions; 2) Dr. MacLean's opinions are reliable because, according to the Defendants he and his team: (i) followed three separate protocols in conducting his experiments; (ii) properly maintained laboratory documentation; (iii) used a proper sample size in his experiments; (iv) used analytical techniques in the experiment consistent with the scientific method; 3) Dr. MacLean properly relied on Ethicon's Seven-Year Dog Study; 4) Dr. MacLean's molecular weight calculations based on data from Plaintiffs' experts are consistent with sound scientific method and principles.

As a preliminary matter, the Defendants erroneously suggest that all of Dr. Iakovlev's degradation opinions are "dependent on his alleged detection of a degraded bark layer on the surface of PROLENE" and that because the one or two intentionally oxidized TVT samples used in Dr. MacLean's unreliable experiment did not "trap or otherwise hold histological stains" they argue Dr. Iakovlev's opinions are unreliable.[17] Defendants also misrepresent the purpose of an ongoing experiment that Dr. Iakovlev is conducting. Contrary to the Defendants misrepresentation, Dr. Iakovlev does not rely solely on his histological evaluation of explanted TVT devices in reaching his degradation opinions. As Dr. Iakovlev's report makes clear, he relied on the totality of the evidence including but not limited: 1) his knowledge, training and experience as a pathologist; 2) his histological analysis of explanted TVT devices; 3) his microscopic analysis of TVT mesh fibers immediately after removal from the body which was not placed in formalin or otherwise processed histological but still showed surface cracking; 4)

[16] Mullins, et al. v. Ethicon, Inc. et al, 2:12-cv-02952, Doc. 227 (Nov. 9, 2015)
[17] See Defendants' Response at pp. 1-2.

his review of the medical and scientific publications that have consistently concluded for more than fifty years that polypropylene including PROLENE degrades after it is implanted in the human body; 5) his review of Ethicon's internal documents demonstrating that PROLENE degrades; and 6) his review of Ethicon's internal studies including studies conducted by Ethicon's scientists who concluded that PROLENE degrades using the same reliable histological methods employed by Dr. Iakovlev.[18]

Moreover, while Dr. Iakovlev continues to work on and study issues of degradation related to mesh as he described during his deposition.[19] Those studies, however, are not designed to test whether "the cracks in degraded Prolene trap histological stains," as Ethicon argues. Instead, Dr. Iakovlev is conducting separate testing to determine whether he can replicate *in vitro* what he sees *in vivo* and will study the *in vitro* degradation using the same methodology and tests that he uses to study the *in vivo* degradation. The entire purpose of the examination is to tell him if the pristine mesh has indeed become degraded in the *in vitro* medium – has he been able to recreate *in vitro* the degradation that he sees *in vivo* -- and <u>not</u>, as Ethicon claims, to determine whether the H&E staining and polarized light can accurately identify degradation. The later – the existence of degradation bark through the processes used by Dr. Iakovlev – is the very test used to determine whether the *in vitro* environment recreates the *in vivo* environment. In short, this testing is not designed to examine any "hypothesis" related to the opinions offered in this case or to prove or disprove any degradation opinions.

[18] See the Expert Report of Dr. Iakovlev attached as Ex. A to Defendants' Response and Plaintiffs' Response to Defendants' Motion to Exclude the Opinions and Testimony of Vladamir Iakovlev, M.D., 2:12-cv-02952, Doc. 190 (11/2/15) at p. 7-8.

[19] See Plaintiffs' Response to Defendants' Motion to Exclude the Opinions and Testimony of Vladamir Iakovlev, M.D., 2:12-cv-02952, Doc. 190 (11/2/15) at p. 7-8.

## ARGUMENT

### I. Dr. Maclean is not Qualified to Offer Opinion Regarding Pathology

Defendants admit that Dr. MacLean is not an expert pathologist.[20] Indeed, Dr. MacLean admitted during his deposition that he is not a pathologist and is not an expert in pathology or histopathology analysis:

> Q. You're not a pathologist?
>
> A. Correct.
>
> Q. And you're not an expert in pathology or histopathology analysis, correct?
>
> A. Correct.[21]

Moreover, when asked if he routinely uses histological staining, Dr. MacLean admitted that does not and that this was the first time that he has ever asked that histological staining be conducted.

> Q. Do you routinely use histological staining?
>
> A. I do not.
>
> Q. When was the last time, other than this case, that you asked for or ordered some H&E staining to be done of explanted specimens?
>
> A. This was the first time that I've actually done that, and that's exactly why we went to a third-party lab that specializes in it.[22]

Despite this, Dr. MacLean offers opinions concerning pathology and disputes the findings and opinions of Dr. Iakovlev and those of other experienced pathologists, including Ethicon's own, who have actually examined explanted PROLENE using the same histological methods employed by Dr. Iakovlev and concluded that explanted PROLENE degraded *in vivo* as

[20] Response at p. 5 ("Dr. MacLean never claimed to be a veterinarian or a pathologist").
[21] MacLean Dep. at 37:1-5.
[22] *Id.*, at 395:4-11

demonstrated through histological staining and polarized light microscopy.

For example, on May 2, 1984, Ethicon's scientists examined six samples of explanted PROLENE sutures by light microscopy.[23] The method used by Ethicon's pathologists was nearly identical to the histological methods employed by Dr. Iakovlev: "Pieces of tissue containing cross-sections of PROLENE suture were submitted for **histological preparation and staining with 1% aqueous Phloxine solution to enhance the visualization of the cracked layer."**[24] Ethicon's scientists reported that "histological sections of sample 6, a cracked surface layer measuring 3.0-4.5 microns was seen, accounting for approximately 8.5% of the total cross-sectional area."[25]

Just as Dr. Iakovlev describes in his report, Ethicon's own scientists observed that the cracked layer "was birefringent when examined under polarized light microscopy" and also as Dr. Iakovlev found "**Phloxin stain had completely penetrated the cracked layer**, Figure 5, or was confined to the periphery of the surface layer, Figure 6."[26] Ethicon's scientists observed that "**[p]articles of blue dye were evidence within the cracked layer**, Figure 5."[27] Ethicon's scientists concluded:"[i]t was shown that a 5-0 PROLENE suture in residence within a human vascular graft for 7 years displayed surface cracking….The cracked layer appeared blue in gross specimens **and blue dye particles were evidence in histological sections of the layer**. **This would indicate that the layer is dyed PROLENE polymer and not an isolated protein**

[23] See e.g., Exhibit J – Examination of Prolene (Polypropylene) Sutures from Human Cardiovascular Explants memo (May 2, 1984) , ETH.MESH.15955462 (Ethicon's scientists using the same histological methods as Dr. Iakovlev found that the explanted PROLENE suture had degraded in vivo. The histological stain penetrated the degraded PROLENE fiber. Blue dye particles were observed within the cracked layer confirming that cracked layer was PROLENE polypropylene and not a protein coating on the PROLENE strands)
[24] *Id.* at ETH.MESH.15955463
[25] *Id.* at ETH.MESH.15955464
[26] *Id.*
[27] *Id.*

**coating on the stands**."[28] Thus, Ethicon's own pathologist using the same histological methods that Dr. Iakovlev used reached the identical conclusions and opinions of Dr. Iakovlev.

Dr. MacLean's criticisms to Dr. Iakovlev's opinions are based almost exclusively on his unreliable experiment where he intentionally oxidized one sample of TVT mesh using chemicals and one sample of TVT mesh using UV-Oxidation and because he could not demonstrate that these "intentionally" oxidized samples trapped histological stains, he argues that Dr. Iakovlev's opinions are unreliable. Dr. MacLean argues that because he could not reproduce the findings of Dr. Iakovlev, then Dr. Iakovlev must be wrong. However, there are other logical explanations for Dr. MacLean's findings.

One explanation is that Dr. MacLean's *ex vivo* experiment did not mimic the long-term *in vivo* degradation process that occurs after the TVT mesh is implanted in the body as demonstrated by Dr. Iakovlev and others. Another explanation is that the samples that Dr. MacLean submitted for histological staining were not oxidized. Because of Dr. MacLean's poor record keeping, it is impossible to verify through contemporaneous lab notebooks what samples were actually subjected to the Chemical and UV experiment and Dr. MacLean and his team did not perform SEM or FTIR on the samples submitted for histological staining to confirm they were oxidized. Finally, another explanation is that Dr. MacLean's findings were by chance but because he and his team failed to use an adequate sample size, we do not know whether his findings are reproducible.

## II. Dr. MacLean's Experiment Did Not Mimic The *In Vivo* Degradation Process

As described in Plaintiffs' Motion, Dr. MacLean attempted to intentionally oxidize samples of TVT mesh by exposing samples to certain oxidizing agents for a period of four and a half weeks. He also attempted to oxidize samples by exposing the samples to ultra-violate light

[28] *Id*. at ETH.MESH.15955464-5465. See also *Id*. at ETH.MESH.15955468.

in a QUV weathering machine for five days. Upon completing these steps, Dr. MacLean sent one sample of each to a pathology laboratory to be processed and stained with Hematoxylin and Eosin (H&E) stains. According to Dr. MacLean, neither sample trapped the H&E stains. However, exposing a TVT sample to oxidizing chemicals for only four and a half weeks is not long enough to mimic long-term *in vivo* degradation that would be detectible using histology techniques, as Dr. Iakovlev explained during his deposition:

> Q. Thank you. Have you have discussed with Dr. Guelcher the results of his test?
>
> A. Yes, I asked him what he saw.
>
> Q. And what did he tell you?
>
> A. He said that there is flaking on the surface early, it's not confluent but there are some flakes forming. I said it might be too early, because he did it I think on six weeks or so, maybe more, maybe up to three months. I said, well, I keep my specimens for at least a year and a half because I believe that that's much time you need to make it visible by my techniques. Maybe by SCM we can see a little bit earlier, and we stopped at that.[29]
>
> ***
>
> Q. Did you have discussions with Dr. Guelcher about trying to stain the polypropylene that he had intentionally oxidized?
>
> A. He asked me. I said it's too early.[30]

Additionally, the mechanism of oxidation that occurs by UV radiation is not the same as *in vivo* degradation. As Dr. Shelby Thames states in his expert report regarding UV light, "the effect of light is not a factor because the mesh is not exposed to ultraviolet (UV) light *in vivo…*"[31] The scientific publications also confirm this[32] as do Ethicon's internal documents:

[29] Deposition of Dr. Vladamir Iakovlev, Sept. 9, 2015, at 40:19-41:9
[30] *Id.* at 41:19-23
[31] Exhibit N - Expert Report of Shelby Thames, Ph.D. (Sept. 15, 2015) at p. 4.
[32] See e.g., Ex. C - Exhibit F – Wood, et al. "Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient" *J. Mater. Sci.*

> Although studies on PROLENE microcracks have been on-going for some time, the bulk of the actual work has been centered about **laboratory experiments which seek to replicate the process through physico-chemical processes, e.g., photo-oxidation**, stress-cracking, etc. These experiments have not been able to produce, from the control material, samples with all the requisite characteristics of the explants.[33]

## III. The Samples Submitted for Histological Staining Where Not Oxidized

The crux of Dr. MacLean's opinions is that oxidized mesh does not trap stain. Therefore, it was imperative for him and his team to establish that the samples submitted for histological staining were oxidized. However, Dr. MacLean cannot verify this because he and team failed to maintain adequate laboratory notebooks or documentation. Additionally, Dr. MacLean and his team failed to perform SEM and FTIR analysis on the samples that were sent for histological staining to confirm the samples were oxidized.

### A. Poor Record Keeping Makes It Impossible to Verify Dr. MacLean's Findings

As illustrated in Plaintiffs' Motion, the Defendants failed to adequately maintain contemporaneous laboratory records such that it is impossible to verify that Dr. MacLean and his team did what they claim to have done. *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579, 593 (1993). In their Response, the Defendants incorrectly claim that Dr. MacLean and his team "recorded all of their actions and procedures in laboratory documentation" and that "]t]he laboratory documentation includes all of the steps taken during the experiment."[34] This simply is not the case. While the Defendants did produce some documentation, they did not produce a laboratory notebook or some other record that verifies, for example, that Dr. MacLean or one of his team members actually treated the samples that were sent for histological staining with

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*Mater. Med.*, (2013) 24(4):1113–1122 at p. 1114 ("Synthetic meshes are recognized as foreign bodies and thus, are subjected to various enzymatic attacks by the body. The primary attack on the material is from neutrophils and macrophages, which are stimulated upon injury or implantation. The cells release lysosomal enzymes and oxidants that can actively break down some of the mesh materials");

[33] See e.g., Exhibit M – ETH.MESH.15958445 (emphasis added).

[34] Defendants' Response at p. 9.

Chemicals or with UV radiation. Tellingly, Defendants did not cite to a single exhibit in their Response verifying what samples were actually treated in the QUV accelerated weathering machine.

### B. Dr. MacLean Failed to Perform SEM and FTIR Analysis on the Samples Submitted for Histological Staining

The Defendants admit that they did not analyze the samples submitted for histological staining with SEM or FTIR to confirm that those samples were actually oxidized. However, they incorrectly argue that the microphotograph images that they produced demonstrate "conclusively establish the presence of cracks on the intentionally oxidized Prolene fibers."[35] However, what the Defendants now claims are "cracks" caused by oxidation is actually just an artifact known in the field of pathology as "chatter".[36] In other words, the microtome blade scratched the fiber during cross-sectioning causing an artifact which is far from "conclusive" evidence establishing these samples oxidized. Dr. MacLean's failure to perform SEM and FTIR to demonstrate that these samples were actually degraded is suspect and the excuses offered in his untimely affidavit should be ignored.

## IV. Dr. MacLean's Findings Were By Chance

Another explanation for Dr. MacLean's findings is that they were by chance. In order to demonstrate that his findings were reproducible and not a coincidence or caused in error, Dr. MacLean should have used more than one QUV-treated sample and more than one Chemically-treated in his histology experiment. Recognizing these flaws, the Defendants procured and attached to their Response Dr. MacLean's untimely affidavit in which Dr. MacLean attempts to justify his use of an insufficient sample size by claiming that because each of the samples had more than one fiber he used more than one sample. While perhaps Defendants should be

[35] Defendants' Response at p. 13.
[36] Exhibit O at pp. 87-88

credited for their creativity, this excuse should be outright rejected as his experiment is no more reliable than the experiment performed by Dr. Barker which was excluded by this Court in *Sanchez et al. v. Boston Scientific Corp.*, 2:12-cv-05762, Doc. 148 (Sept. 29, 2014).

In *Sanchez*, Dr. Barker tested one piece of Obtryx and two pieces of Pinnacle mesh by cutting strips of the mesh from pristine products and attaching them to clamps. Each strip of mesh within his sample contained multiple fibers and multiple pores, like the two samples used by Dr. MacLean in his experiments; however, this Court ruled that "Dr. Barker's testing of merely one or two samples lacks reliability."[37]

**V. Dr. MacLean's Opinions Regarding the Seven-Year Dog Study Are Unreliable**

Defendants argue that Dr. MacLean's reliance on the molecular weight data from Ethicon's Seven-Year Dog study which was derived from comparing an explanted PROLENE 5/0 suture implanted in 1985 to a PROLENE 4/0 suture in 1992 was proper. In support of this, Defendants cite to portions of Dr. MacLean's deposition testimony where he opines, without any factual or meaningful scientific basis other than his say-so, that the molecular weight of a Prolene 4-0, 5-0, 6-0 are essentially the same.[38] However, Dr. MacLean's say-so does not demonstrate reliability. Dr. MacLean has not even attempted to verify these opinions and the evidence demonstrates the opposite. According to Ethicon's internal documents, Prolene 6-0 suture has a molecular weight of 358,000 and a molecular number of 83,000.[39] The Prolene 4-0 suture used as a control the 1992 Seven-Year Dog Study has different molecular weight and a different molecular number (324,000/60,000). Thus, having failed to demonstrate that the explanted 1985 Prolene 5-0 suture shares the same molecular weight as the 1992 Prolene 4-0 suture used as a control, Dr. MacLean's reliance on the Seven-Year Dog Study amounts to

[37] *Id*. at p. 13
[38] See e.g., Defendants' Response at pp. 16 and 17.
[39] Exhibit Q - Internal Ethicon Laboratory Notebook, ETH.MESH.00005605

nothing more than speculation and guesswork, which should be excluded. Rosen v. Chiba-Geigy Corp., 78 F.3d 316, 318-19 (7th Cir. 1996) (stating that "the courtroom is not the place for scientific guesswork, even of the inspired sort").

## VI. Dr. MacLean's Molecular Weight Calculations Are Unreliable

The Defendants argue that Dr. MacLean's calculations of molecular weight derived from the data generated by Plaintiffs' experts are reliable. However, it is clear from Dr. MacLean's own report that he is cherry picking data to come to a calculation that supports his opinion. In his general expert report, Dr. MacLean writes "[a]ccording to Ethicon's documents, the depth of microcracks in explanted PROLENE sutures has been measured to be 0.5 – 4.5 microns."[40] Indeed, other internal Ethicon documents, the crack depths are measured between 0.7 to 1.3 microns.[41] Yet, Dr. MacLean assumes the depths of the cracks in the Dog Study are 4 microns. The reason he does this is obvious: he knows that a crack depth somewhere below 4 microns invalidates his calculations:

> Q. So if you assume 4 microns, it gets you outside of the standard deviation for the molecular weight?
> A. At 4 microns, it does, correct.
> Q. At 2 microns, it gets you closer to the bulk analysis, which would wash out the molecular weight changes on the surface, they'd be masked by the bulk?
> A. It could. Yeah, at some smaller crust thickness, you would be within the statistical confines of the original data.[42]

Dr. MacLean should not be permitted to cherry-pick data from various different studies and test subjects to support his assumption that the crack depth from Ethicon's Seven-Year Dog Study measure 4 microns, especially where other internal Ethicon documents describe small crack depths which Dr. MacLean apparently disregards.

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[40] MacLean Expert Report attached to Plaintiffs' Motion as Exhibit 1 at p. 24 (citing ETH.MESH.123831405)
[41] Exhibit P
[42] MacLean Dep. at 278:23-279:8 attached as Exhibit 4 to Plaintiffs' Motion.

## CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court grant their Motion to Exclude or, Alternatively, Limit the Opinions and Testimony of Dr. Maclean, Ph.D., P.E.

Dated: November 17, 2015

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 17, 2015, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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